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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,916	10/10/2001	Peter M. Thule	US 1292/01 (VA)	4645
7590 12/01/2009 Law Office - Dinesh Agarwal, P.C. 5350 Shawnee Road, Suite 330 Alexandria, VA 22312			EXAMINER	
			ANGELL, JON E	
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
12/01/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/972,916	<b>Applicant(s)</b> THULE, PETER M.
	<b>Examiner</b> J. E. ANGELL	<b>Art Unit</b> 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

1) Responsive to communication(s) filed on 01 September 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-15 and 17-21 is/are pending in the application.  
 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-15 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449)  
 Paper No(s)/Mail Date 9/1/09

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date: \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

This Action is in response to the communication filed on 9/1/2009.

The amendment filed 9/1/2009 is acknowledged and has been entered.

1. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

#### ***Status if the Claims***

Claims 1-15 and 17-21 are currently pending.

Claims 17-21 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/21/2004.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Diabetes May 1999, supplement— previously cited) as evidenced by Thule and Liu presentation

at the ADA 59<sup>th</sup> Annual Meeting, June 1999 (provided as Reference 3 in the IDS filed 3/14/2006) and Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), for the reasons of record.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Abstract from meeting June 9-13, 1999, previously cited) as evidenced by Thule and Liu presentation at the American Society of Gene Therapy 2<sup>nd</sup> Annual Meeting, June 1999 (provided as Reference 4 in the IDS filed 3/14/2006) and Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743) for the reasons of record.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Abstract from meeting of June 1998—previously cited) as evidenced by Thule and Liu presentation at the ADA 58<sup>th</sup> Annual Meeting, June 1998 (provided as Reference 2 in the IDS filed 3/14/2006) and Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), for the reasons of record.

***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thule et al (Diabetes May 1999, supplement— previously cited) in view of Thule and Liu presentation at the ADA 59<sup>th</sup> Annual Meeting, June 1999 (provided as Reference 3 in the IDS filed 3/14/2006) and further in view of Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), Vaulont

et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Cognet et al. (J. Mol. Biol. 1987, cited by Applicants), for the reasons of record.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thule et al (Abstract from meeting June 9-13, 1999, previously cited) in view of Thule and Liu presentation at the ADA 59<sup>th</sup> Annual Meeting, June 1999 (provided as Reference 3 in the IDS filed 3/14/2006) and further in view of Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Cognet et al. (J. Mol. Biol. 1987, cited by Applicants), for the reasons of record.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thule et al Thule et al (Abstract from meeting of June 1998—previously cited) in view of Thule and Liu presentation at the ADA 59<sup>th</sup> Annual Meeting, June 1999 (provided as Reference 3 in the IDS filed 3/14/2006) and further in view of Goswami et al. (Endocrinology 1994, Vol. 134, pages 736-743), Vaulont et al. (J. Mol. Biol. 1989, Vol. 209, pages 205-219) and Cognet et al. (J. Mol. Biol. 1987, cited by Applicants), for the reasons of record.

*Response to Arguments*

1. Applicant's arguments and the Declaration of Dr. Thule filed 9/1/2009 have been fully considered but are not fully persuasive.
2. As acknowledged by Applicants, the rejections under 35 USC 102 have been extensively discussed in prior actions. For the reasons discussed therein, the rejections are maintained.

3. Applicants argue that the Examiner has improperly relied on Applicant's own specification in forming the 103 rejection asserting that the rejection is based on hindsight reasoning.

4. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

5. Applicants argue (including Dr. Thule in his Declaration) that SEQ ID NO:5 encompasses sequences -173 to -123 and -114 to +105 of rL-PK and rIGFBP-1, respectively, which is different than the sequences taught in the presentations. In response, it is respectfully pointed out that the instant claims are not limited to SEQ ID NO:5. Rather, claim 9 indicates that the construct can comprise any of SEQ ID NO: 3-6. Therefore, the argument is not fully persuasive. It is noted however, that limiting the claims to SEQ ID NO:5 would obviate the instant rejections.

6. Applicants argue (including Dr. Thule in his Declaration) that there would not have been a reasonable expectation of success in making the invention, based on the failed experiments of others. In other words, Applicants believe that it was unexpected that combining the elements as claimed would result in a functional construct. This is not persuasive because the expectation of success is based on the teachings of the presentations which indicate that combining the elements

as claimed would result in a functional construct. Thus, regardless of the other results, the presentations clearly indicate that combining the elements as claimed would result in a functional construct, thus providing a reasonable expectation of success.

7. Therefore, Applicants arguments are not persuasive.

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. ANGELL whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore can be reached on 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. ANGELL/  
Primary Examiner, Art Unit 1635